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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)		Application Number	10/820,656
		Filing Date	April 8, 2004
		First Named Inventor	Robert G. Schaub
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	7	Attorney Docket Number	50657-00004USPT

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): SB/08, copies of non-patent literature, cert. of mailing, postcard
<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	JENKENS & GILCHRIST, A PROFESSIONAL CORPORATION Tamsen Valoir, Ph.D., Reg. No. 41, 417
Signature	
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Dated: July 20, 2004	Signature:  (Diane Bergin)

Application No. (if known): 10/820,656

Attorney Docket No.: 50657-00004USPT

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Signature:

*Diane Bergin*  
(Diane Bergin)

Docket No.: 50657-00004USPT  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Robert G. Schaub et al.

Application No.: 10/820,656

Confirmation No.:

Filed: April 8, 2004

Art Unit: Not Yet Assigned

For: HEMOPHILIA TREATMENT BY  
INHALATION OF COAGULATION  
FACTORS

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
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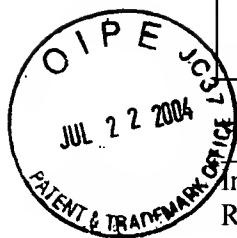
Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

A copy of each reference which is listed as "non-patent literature" on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any



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Docket No.: 50657-00004USPT

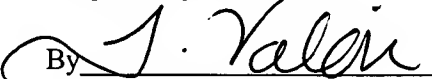
patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 10-0447, under Order No. 50657-00004USPT.

Dated: July 20, 2004

Respectfully submitted,

By 

Tamsen Valoir, Ph.D.

Registration No.: 41,417

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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	3	Attorney Docket Number	50657-00004USPT
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**Complete if Known**

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First Named Inventor	Robert G. Schaub
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	50657-00004USPT

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-6,518,239	02-11-2003	Mei-Chang Kuo	
	AB	US-6,372,258	04-16-2002	ROBERT M. PLATZ	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Liles D, et al., Extravascular administration of Factor IX: Potential for replacement therapy of canine and human hemophilia B. Thromb Haemost 1997; 77: 944-8.	
	CB	Patton JS, Platz RM. Pulmonary delivery of peptides and proteins for systemic action. Adv Drug Del Rev 1992; 8: 179-96.	
	CC	Hubbard RC, et al., Fate of aerosolized recombinant DNA-produced alpha1-antitrypsin: Use of epithelial surface of the lower respiratory tract to administer proteins of therapeutic importance. Proc Natl Acad Sci 1989; 86: 680-4.	
	CD	Brinkhous KM, et al., Recombinant human Factor IX: Replacement therapy, prophylaxis, pharmacokinetics, and immunogenicity in canine hemophilia B. Blood 1996; 88: 603-10.	
	CE	Russel KE, et al., Intratracheal administration of recombinant human Factor IX (BeneF.IX™) achieves therapeutic levels. Blood 1998; 92: 356a.	
	CF	Evans JP, et al., Canine Hemophilia B resulting from a point mutation with unusual consequences. Proc Natl Acad Sci USA 1989; 86: 10095-9.	
	CG	Kay MA, et al., In vivo gene therapy of hemophilia B: Sustained partial correction in Factor IX-deficient dogs. Science 1993; 262: 117-9.	
	CH	Herzog R, et al., Absence of circulating Factor IX antigen in hemophilia B dogs of the UNC Chapel Hill Colony. Thromb Haemost 2000; 84: 352-4.	
	CI	Harrison S, et al., Development of a serum-free process for recombinant Factor IX expression in Chinese hamster ovary cells. Thromb Haemost 1995; 73: 1222.	
	CJ	Foster WB, et al., Development of a process for purification of recombinant human Factor IX. Blood 1995; 86: 870a.	
	CK	Rodrigues H, et al., Analytical characterization of recombinant human Factor IX: Pharmacokinetic studies in the rat and the dog. Thromb Haemost 1995; 73: 1206.	
	CL	Keith JC, et al., Evaluation of recombinant human Factor IX: Pharmacokinetic studies in the rat and the dog. Thromb Haemost 1994; 73: 101-5.	

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/820,656
				Filing Date	April 8, 2004
				First Named Inventor	Robert G. Schaub
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	50657-00004USPT

CM	Lee RI, White PD. A clinical study of the coagulation time of blood. Am J Med Sci 1913; 145: 495-503.
CN	Brinkhous KM, et al., Evaluation of sensitivity of whole blood clotting time (WBCT), partial thromboplastin time (PTT), and F.IX one-stage bioassay tests with low plasma F.IX levels observed with transfusion or gene therapy in canine hemophilia B. Blood 1993; 82 (Suppl 1): 592a.
CO	Mustafa RL, et al., A role for whole blood clotting time as a sensitive screening test for F.VIII and F.IX replacement. Blood 1998; 92: 96b.
CP	Pedersen PV. Novel Deconvolution Method for Linear Pharmacokinetic Systems with Polyexponential Impulse Response. J Pharm Sci 1980; 69:312-8.
CQ	Gerrard AJ, et al., Subcutaneous injection of Factor IX for the treatment of haemophilia B. British Journal of Haematology 1992; 81: 610-3.
CR	McCarthy KP, et al., Subcutaneous bioavailability of recombinant Factor IX (BeneF.IX™) in healthy beagle dogs and cynomolgus monkeys. Blood 1996; 88: 68b.
CS	Cheung WF, et al., Identification of the endothelial cell binding site for Factor IX. Proc Natl Acad Sci USA 1996; 93: 11068-73.
CT	Wolberg AS, et al., Human Factor IX binds to specific sites on the collagenous domain of collagen IV. J Biol Chem 1997; 272: 16717-20.
CU	Brinkhous KM, et al., Subcutaneous recombinant Factor IX (BeneF.IX™) administration produces therapeutic levels of F.IX activity in hemophilia B dogs. Blood 1996; 88: 422a.
CV	Yu J, Chien YW. Pulmonary drug delivery: Physiologic and mechanistic aspects. Crit Rev Therap Drug Carr Sys 1997; 14: 395-453.
CW	Brain JD, et al., Pulmonary distribution of particles given by intratracheal instillation or by aerosol inhalation. Environ Res 1976; 11: 13-33.
CX	Colthorpe P, et al., The pharmacokinetics of pulmonary-delivered insulin: A comparison of intratracheal and aerosol administration to the rabbit. Pharm Res 1992; 9: 764-8.
CY	Gillespie MN, et al., Pulmonary metabolism of exogenous enkephalins in isolated perfused rat lungs. J Pharmacol Exp Ther 1985; 232: 675-8.
CZ	Jendle J, et al., Delivery and retention of an insulin aerosol produced by a new jet nebulizer. J Aerosol Med 1995; 8: 243-54.
CA1	Jendle JH, et al., An exploration of intrapulmonary insulin administration in anaesthetized and mechanically ventilated pigs. Scand J Clin Lab Invest 1996; 56: 251-8.
CB1	Laube BL, et al., Preliminary study of the efficacy of insulin aerosol delivered by oral inhalation in diabetic patients. JAMA 1993; 269: 2106-9.
CC1	Gupta S, et al., Pulmonary delivery of human protein C and Factor IX, in (ed) NaL (ed): Oxygen Transport to Tissue XVIII. New York: Plenum Press 1997; p 429-35.
CD1	Wigley FM, et al., Insulin across respiratory mucosae by aerosol delivery. Diabetes 1971; 20: 552-6.
CE1	Lusher JM. Thrombogenicity associated with Factor IX complex concentrates. Semin Hematol. 1991;28(3 supp.6):3-5.
CF1	Shapiro AD, Ragni MV, Lusher JM, et al. Safety and efficacy of monoclonal antibody purified IX concentrates in previously untreated patients with hemophilia B. Thromb Haemost. 1996;75(1):30-35.
CG1	Roberts HR, Eberst ME. Current management of hemophilia B. Hemat Oncol Clin North Am. 1993;7(6):1269-1280.
CH1	Kasper CK, et al. A more uniform measurement of factor VIII inhibitors. Thromb Diathes Haemorrh 34:869-872, 1975.
CI1	Giles AR, A detailed comparison of the performance of the Standard versus Nijmegen modifications of the Bethesda Assay in detecting factor VIII. Thromb. Haemost 79:872-5,

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	1998.	
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<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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